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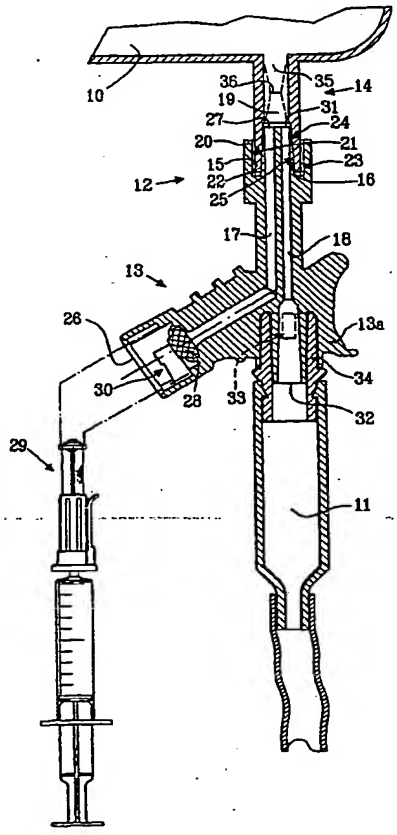
(54) Title: A COUPLING COMPONENT FOR TRANSMITTING MEDICAL SUBSTANCES



(57) Abstract: A coupling component (13) for transmitting medical substances, comprising two channels (17, 18) for conveyance of medical substances in two substantially opposite directions and a means (21) for releasable connection to a second coupling component (14) having a further channel (19), for creating a coupling (12). The connecting means is a thread (21).

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ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

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A coupling component for transmitting medical substances

FIELD OF THE INVENTION AND PRIOR ART

The present invention relates to a coupling component for transmitting medical substances, comprising two channels for conveyance of medical substances in two substantially opposite directions and a means for releasable connection to a second coupling component having a further channel, for creating a coupling. Furthermore, the invention relates to a coupling for transmitting medical substances, comprising a first component having two channels for conveyance of medical substances in two substantially opposite directions, a second component having a further channel and a means for releasable connection of the first and the second component to each other for creating the coupling. The invention also relates to a method for conveyance of medical substances to and from a container, in which method a coupling component having two channels for conveyance of medical substances in two substantially opposite directions be connected to a second coupling component of a container, which second coupling component has a further channel.

The invention may be applied in different situations when medical substances are to be handled, but hereinafter the particular, but not in any way limiting for the invention, fields of application constituting a means for administration of fluids to/from infusion bags, which is desired in medical treatment for instance, will be described for illuminating purposes.

Infusion bags are used for intravenous delivery of fluids and medically effective substances to human beings and animals. For this reason, the infusion bag is provided with an outlet through which fluid may flow to a component connected to the patient, such as a cannula or the like, and further into the body of the patient. When preparing the fluids which are to be administrated to the body from the infusion bag, a usual method is that medically effective substances are supplied to a pre-sealed infusion bag which is filled with a transport fluid, such as a sodium chloride solution or a glucose solution. The preparation is performed by injecting the medically effective substance via an inlet into the bag.

For accomplishing the desired transportations of fluid a combined inlet and outlet of the infusion bag together with a coupling device which is denoted "spike" are often used. The spike has a first pointed end by means of which a membrane arranged in a narrow

passage of the infusion bag, constituting inlet/outlet of the infusion bag, may be penetrated so that the infusion bag be opened towards two channels arranged in the spike when the spike is introduced in the inlet/outlet of the infusion bag. One of the channels is intended for conveyance of fluid in a direction from the infusion bag towards the patient and the other channel is intended for injection of medical substances into the infusion bag. In the other end of the spike are members arranged at the mouths of the channels for connection to other components, such as flexible tubes for conveyance of the fluid further to the patient and cannulas for the injection of medical substances to the infusion bag.

However, it has appeared that during certain extreme conditions there is a risk that the spike, which by insertion in the above mentioned narrow passage of the infusion bag is relatively loosely interconnected to the infusion bag, may unintentionally come loose from the infusion bag if the equipment is handled carelessly or by carelessness in connection with other treatment of the patient. The system of spike and infusion bag is depended of the friction between the infusion bag and the spike to prevent the spike from coming loose from the infusion bag. Furthermore, the spike has the disadvantage that leakage from the infusion bag to the environment may occur when the spike is introduced and the membrane is penetrated. In some cases the fluids which are to be administrated to the patient may be harmful to other persons than the patient who has been prescribed the treatment as a result of an indication of a specific decease. This is particularly the case when repeated long-term exposure is concerned, which can happened to medical staff when preparing and connecting infusion bags every day if the requisite security regulations are not fulfilled. A further disadvantage with the use of a spike which during the connection penetrates a membrane of the infusion bag for providing the fluid administration channels is that the connection step itself cannot be made in advance to later on enable conveyance of fluid from the infusion bag to a receiving unit connected to the spike, but the channels have to be opened instantaneously at the connecting moment.

THE OBJECT OF THE INVENTION AND SUMMARY OF THE INVENTION

One object of the invention is to provide a coupling component/coupling of the kind defined by way of introduction for transmitting medical substances, in which coupling component/coupling at least some of the discussed disadvantages of such previously known coupling devices has been reduced to a great extent.

This object is achieved by providing a coupling component according to claim 1 and a coupling according to claim 8. By a coupling component/coupling having the feature

that the connecting means is a thread/a thread joint it is ensured that the coupling not be unintentionally uncoupled when the coupling is tension loaded. By means of the thread/thread joint a coupling safe against tension load may be obtained at the same time as the connection may be accomplished quickly and safely in one simple operation. This implies that in the use of a device according to the invention, when an infusion bag is connected to a patient, an increased safety to the patient may be achieved at the same time as it is possible to deliver medical substances to the infusion bag and intravenously administrate fluid to the patient from the infusion bag. Furthermore the invention enables the use of other means, such as breakable fluid barrier plugs, for opening the infusion bag towards the channels and there is possible to ensure that leakage to the environment is prevented by tightening the thread joint before the infusion bag be opened towards the channels.

A further object of the invention is to provide a method of the kind defined by way of introduction, in which method a container and a coupling component, having two channels for conveyance of medical substances in two substantially opposite directions, may be connected to each other for conveyance of medical substances via the channels without the container being instantaneously opened towards the two channels.

This object is achieved by providing a method according to claim 17. Hereby the connection may be accomplished so as to later on enable conveyance of a medical substance from the container via one first of said two channels and/or conveyance of a medical substance to the container via the other of said two channels.

The invention also relates to an infusion bag according to claim 15 and an infusion arrangement according to claim 16.

SHORT DESCRIPTION OF THE DRAWINGS

A description in greater detail of exemplifying embodiments of the invention will follow below with reference to the attached drawings.

In the drawings:

Fig. 1 is a sectional view of an infusion bag and a spike according to prior art connected to the infusion bag,

Fig. 2 is a sectional view of an infusion bag and a coupling according to the invention for transmitting medical substances, and

Fig. 3 is a sectional view illustrating a variant of the coupling according to invention in Fig. 2.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS OF THE INVENTION

In Fig. 1 an infusion bag 1 and a coupling device 2 of the type called spike according to prior art are illustrated. The coupling device 2 is provided with a pointed part 3 which is introducible in a part 4 which constitutes an inlet/outlet of the infusion bag 1. This part 4 of the infusion bag 1 is designed as a flexible tube with a circular cross-section corresponding to the cross-section of the pointed part 3 of the spike and has, before the introduction of the pointed part of the spike, a sealing membrane arranged at the mouth 5 thereof. In the introduction of the spike the pointed part 3 penetrates the membrane and the infusion bag 1 be opened towards two channels 6, 7 arranged in the spike. Thereafter, medical substances may be injected into the infusion bag 1 via one first 6 of the channels and fluid may be transported out from the bag via the other 7 of the channels to a receiving unit (not illustrated).

In Fig. 2 an infusion bag 10, a receiving unit 11 connected to the infusion bag and a coupling 12 according to the invention are illustrated. The coupling 12 comprises a first component 13, a second component 14 and a means 15 for releasable connection of the first 13 and second 14 components to each other for creating the coupling 12. The first component 13 comprises a male fitting 16 provided with two channels 17, 18 for conveyance of medical substances in two substantially opposite directions. One first channel 17 for injecting medical substances into the infusion bag 10 and one second channel 18 for conveyance of fluid out of the infusion bag 10 to the receiving unit 11, which may be for example a chamber or the like for intravenous treatment. The second component 14 is provided with a further channel 19 intended to be in communication with said two channels 17, 18 of the first component 13.

The connecting means 15 is a thread joint having the characteristic that said first 13 and second 14 components are locked against rectilinear movement relative to each other when being connected to each other and the coupling 12 is tension loaded. The first component 13 has a ring 20 partly enclosing the male fitting 16, which ring has a internal thread 21 constituting part of the thread joint. The ring 20 is concentrically arranged relative to the male fitting 16. The second component 14 comprises a female fitting 22 provided with said further channel 19 and an external thread 23 corresponding to said thread 21 of the ring 20 and constituting part of the thread joint. When the first and second components are to be connected to each other, i.e. when the

first and the second components be screwed together, the male fitting 16 be introduced into the female fitting 22 to form a connection between said two channels 17, 18 of the first component 13 and the further channel 19 of the second component 14, which connection is sealed relative to the environment. For this purpose the male fitting 16 and/or female fitting 22 may be designed with a certain taper so that when the male fitting and the female fitting have been brought together a certain distance the outer surface 24 of the male fitting will abut against the inner surface 25 of the female fitting, and then further movement of the components in the introduction direction relative to each other is not longer possible and a sealing between the male fitting 16 and the female fitting 22 is obtained when tightening the thread joint 15.

Although the coupling component according to the invention, i.e. said first component, which has the both channels, is designed as a male fitting of the coupling in the illustrated example, in another embodiment it could be designed as a female fitting 22a of the coupling 12, such as illustrated in Fig. 3, and the other component, which is arranged on for example an infusion bag, would in such a case be designed as a corresponding male fitting 16a. Of course it is also possible to change places of the threads in comparison to the illustrated embodiment in Fig. 2, so that instead, the second component including the female fitting is provided with an internal thread and the first component including the male fitting is provided with an external thread. The threads may for example be arranged on rings such as described above.

Advantageously the design of the threads 21, 23, the male fitting 16 and the female fitting 22 may be in accordance with a so called luer fitting coupling such as in the illustrated embodiments.

The coupling component 13 according to the invention is provided with a port 26 for injection of a medical substance to the first of the channels 17 and further conveyance of this substance to the infusion bag 10. For this purpose, the first channel 17 has also an outlet 27 arranged at one end of the first coupling component 13 which exhibits the connecting means 15 and the second coupling component 14 has said further channel 19, which communicates with the first 17 and the second 18 channels, for introduction or removal of liquid to/from the infusion bag 10.

Within the frame of the invention the injection port 26 may be designed in different ways depending on which injection component is to be connected. In the illustrated embodiment the injection port 26 has a first flexible membrane 28 for co-operation with a second flexible membrane (not illustrated) arranged in an injection component 29 which is connectable to the injection port 26. The first membrane 28 is suitably air- and

liquid proof and penetratable by an injection needle. To achieve a sealed connection of such a injection component 29 to the injection port 26, the injection port has a means 30 for holding said second flexible membrane with a pressure against said first flexible membrane 28. This holding means 30 may for example be constituted by a snap lock device, bayonet coupling or similar. The current pressure in question may suitably be chosen so that said first and second membranes are pressed together to a pressure exceeding the yield point of the both membranes, which implies that fluid cannot be pressed out through the contact surfaces of the membranes and a sealed connection is obtained.

If a pressure exceeding the yield point is applied the membranes will exhibit same properties at the compressed surfaces as in an arbitrary cross-section through the membranes, which implies that liquid cannot be pressed through the contact surfaces of the membranes. Such a characteristic may be obtained when the said first and second membranes has been pressed together to a pressure exceeding 150 kPa. Since the device risks to be destroyed if it is subjected to exceedingly large contact forces, the contact pressure should be restricted as much as possible. It has been proved in experiments that the sufficient sealing without any risk of failure is obtained with contact forces of up to 11, 1N, which corresponds to 656 kPA. Preferably, the contact pressure is within the interval 300-473 kPa.

At one end of the first coupling component 13, which end exhibits the connecting means 15 for establishing communication with the further channel 19 of the second coupling component 14 of the infusion bag 10, the second channel 18 has a inlet 31. Furthermore, the first coupling component 13 has in the other end thereof a port 32 which works as an outlet for the second channel 18. Within the frame of the invention the outlet port 32 may be designed in several different ways depending on which unit is to be connected to the outlet port. For example a snap coupling 33 may be used in combination with a friction joint for retaining a connection unit at the outlet port. In accordance with an variant thereof the entire coupling component 13, or at least the part 13a closest to the outlet port 32a of the coupling component 13, may be made of a first material and the connection unit 34 corresponding to the outlet port may be made of a second material. In this connection, materials having considerably different elasticity may be chosen, preferably so that the second material has a considerable higher elasticity than the first material for providing sufficient sealing action between the coupling component 13 and the connection unit 34 and at the same time achieve that the coupling component 13 having a lower elasticity has a high resistance against deformation.

In the extension of the further channel 19, i.e. in a combined inlet and outlet 35 of the infusion bag 10 a breakable fluid barrier plug 36 is arranged. In a state of not has been broken the fluid barrier plug 36 prevents in-flowing and out-flowing via the combined inlet and outlet 35 of the infusion bag 10 which implies that the infusion bag 10 is sealed. After connecting the infusion bag 10 to the coupling component 13 according to the invention, and eventually to other components, the fluid barrier plug 36 may be broken so that the combined inlet and outlet 35 of the infusion bag 10 be opened towards the both channels 17, 18 in the coupling component 13 according to the invention.

The method according to the invention comprises connecting of a coupling component 13 having two channels 17, 18 for conveyance of medical substances in two substantially opposite directions to a second coupling component 14 of a container 10, such as a infusion bag 10, which second coupling component has a further channel 19. After the coupling component 13 and the container 10 have been connected to each other, the container 10 be opened by means of a member 36, preferably in the form of a breakable fluid barrier plug or similar, which member is suitably arranged in a combine inlet and outlet 35 of the container 10, towards the both channels 17, 18 for enabling transportation of a medical substance to the container 10 via one first 17 of said two channels, and for enabling transportation of a medical substances from the container 10.

Preferably, the first 13 and the second 14 coupling components are connected to each other by a thread joint 15. By means of the thread joint 15 a male fitting 16 of the first component 13 may be brought into contact with a corresponding female fitting 22 of the second component 14 to form a connection sealed relative to the environment between said two channels 17, 18 and the further channel 19 of the second coupling component 14.

Then, the container 10 be opened towards 17, 18 by breaking the breakable fluid barrier plug 36. Thereafter, a medical substance may be injected to the container via one first 17 of said channels. Advantageously, the medical substance is injected by means of a component via a port arranged in the first coupling component which port has a first flexible membrane for co-operation with a second flexible membrane arranged in the injection component. Preferably, said second flexible membrane is held against said first flexible membrane with a pressure during the injection to prevent leakage and wastage during the injection. It has been proved that by holding said second flexible membrane against said first flexible membrane with a pressure exceeding the yield point of the first and second membranes it is ensured that the

membranes fit tightly to each other in such away that fluid transportation between these membranes is prevented and thereby leakage to the environment is avoided. Parallel with the injection, the liquid state medical substance in the container may be transported via the second 18 of said two channels to a receiving unit.

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It is stressed that the invention is not restricted to the exemplifying embodiments; rather within the scope of protection defined by the following claims, the invention may be varied in several ways once the idea of the invention is disclosed.

CLAIMS

1. A coupling component (13) for transmitting medical substances, comprising two channels (17, 18) for conveyance of medical substances in two substantially opposite directions and a means (21) for releasable connection to a second coupling component (14) having a further channel (19), for creating a coupling (12), **characterized in** that the connecting means is a thread (21).

2. A coupling component according to claim 1, **characterized in** that it comprises a male fitting (16) provided with said two channels (17, 18), which male fitting is intended to cooperate with a corresponding female fitting (22) of said second coupling component (14), which female fitting is provided with said further channel (19), to form a connection sealed relative to the environment between said two channels (17, 18) and said further channel (19).

3. A coupling component according to claim 2, **characterized in** that it comprises a ring (20) which is concentrically arranged relative to the male fitting (16) and at least partly encloses the male fitting, said ring being provided with said thread (21).

4. A coupling component according to any preceding claim, **characterized in** that it is provided with a port (26) for injection of a medical substance to a first (17) of said two channels.

5. A coupling component according to claim 4, **characterized in** that the injection port (26) has a first flexible membrane (28) for cooperation with a second flexible membrane arranged in an injection component (29) which is connectable to the injection port (26).

6. A coupling component according to claim 5, **characterized in** that it comprises a means (30) for holding said second flexible membrane with a pressure against said first flexible membrane (28).

7. A coupling component according to claim 6, **characterized in** that the pressure exceeds the yield point of the first and the second membranes.

8. A coupling component according to claim 6 or 7, **characterized in** that the pressure exceeds 150 kPa.

9. A coupling (12) for transmitting medical substances, comprising a first component (13) having two channels (17, 18) for conveyance of medical substances in two substantially opposite directions, a second component (14) having a further channel (19) and a means (15) for releasable connection of the first and the second components to each other for creating the coupling (12), **characterized in** that the connection means is a thread joint (15).

10. A coupling according to claim 9, **characterized in** that the first component (13) comprises a male fitting (16) provided with said two channels (17, 18) and the second component comprises a corresponding female fitting (22) provided with said further channel (19), to form a connection sealed relative to the environment between said two channels (17, 18) and said further channel (19) when the first and the second components are connected to each other.

11. A coupling according to claim 10, **characterized in** that the first component (13) comprises a ring (20) which is concentrically arranged relative to the male fitting (16) and at least partly encloses the male fitting, which ring is provided with a first thread (21) constituting part of the thread joint (15), and in that the female fitting (22) is provided with a second thread (23) corresponding to said first thread (21) and constituting part of the thread joint (15).

12. A coupling according to any of claims 9-11, **characterized in** that the first component (13) is provided with a port (26) for injection of a medical substance to a first (17) of said two channels.

13. A coupling according to claim 12, **characterized in** that the injection port (26) has a first flexible membrane (28) for cooperation with a second flexible membrane arranged in an injection component (29) which is connectable to the injection port (26).

14. A coupling according to claim 13, **characterized in** that it has a means (30) for holding said second flexible membrane with a pressure against said first membrane (28).

15. A coupling according to claim 14, **characterized in** that the pressure exceeds the yield point of the first and the second membranes.

16. A coupling according to claim 14 or 15, **characterized in** that the pressure exceeds 150 kPa.

17. An infusion bag (10) comprising a coupling according to any of claims 9-16.

18. An infusion arrangement comprising an infusion bag (10) provided with a coupling (12) according to any of claims 9-16, for transmitting a medical substance from an injection component to the infusion bag via one first of the channels and for transmitting a medical substance from the infusion bag to a receiving unit connected to the coupling via the other of the channels.

19. A method for conveyance of medical substances to and from a container (10), comprising connecting a first coupling component (13) having two channels (17, 18) for conveyance of medical substances in two substantially opposite directions to a second coupling component (14) of a container (10), said second coupling component having a further channel (19),
characterized by opening the container (10) towards said two channels (17, 18) after that the first coupling component (13) and the container (10) have been connected to each other, for enabling conveyance of a medical substance from the container (10) via one first (17) of said two channels and conveyance of a medical substance to the container (10) via the other (18) of said two channels.

20. A method according to claim 19, **characterized by** opening the container (10) towards said two channels (17, 18) by breaking a breakable fluid barrier plug (36).

21. A method according to claim 19 or 20, **characterized by** opening the container (10) towards said two channels (17, 18) by means of a member (36) arranged in the container (10).

22. A method according to claim 19, 20 or 21, **characterized by** injecting the medical substance to the container (10) via one first (17) of said two channels.

23. A method according to claim 22, **characterized by** injecting the medical substance by means of a component (29) via a port (26) arranged in the first coupling component (13) which port has a first flexible membrane (28) for cooperation with a second flexible membrane arranged in the injection component (29).

24. A method according to claim 23, **characterized by** holding said second flexible membrane against said first flexible membrane (28) with a pressure when injection is performed.

25. A method according to claim 24, **characterized by** holding said second flexible membrane against said first flexible membrane (28) with a pressure exceeding the yield point of the first and the second membranes.

26. A method according to claim 24 or 25, **characterized by** holding said second flexible membrane against said first flexible membrane (28) with a pressure exceeding 150 kPa.

27. A method according to any of claims 19-25, **characterized by** connecting the first coupling component (13) and the second coupling component (14) of the container (10) by means of a thread joint (15).

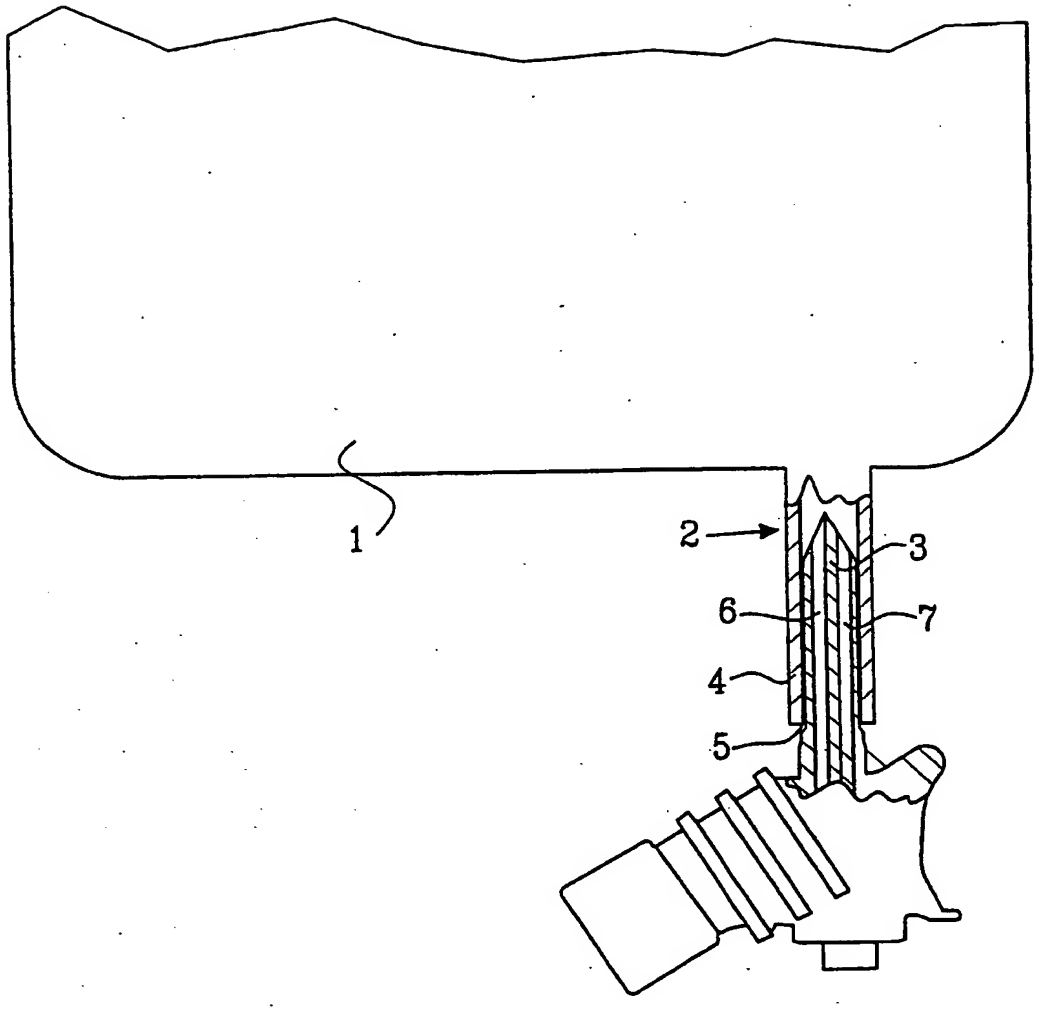

FIG.1

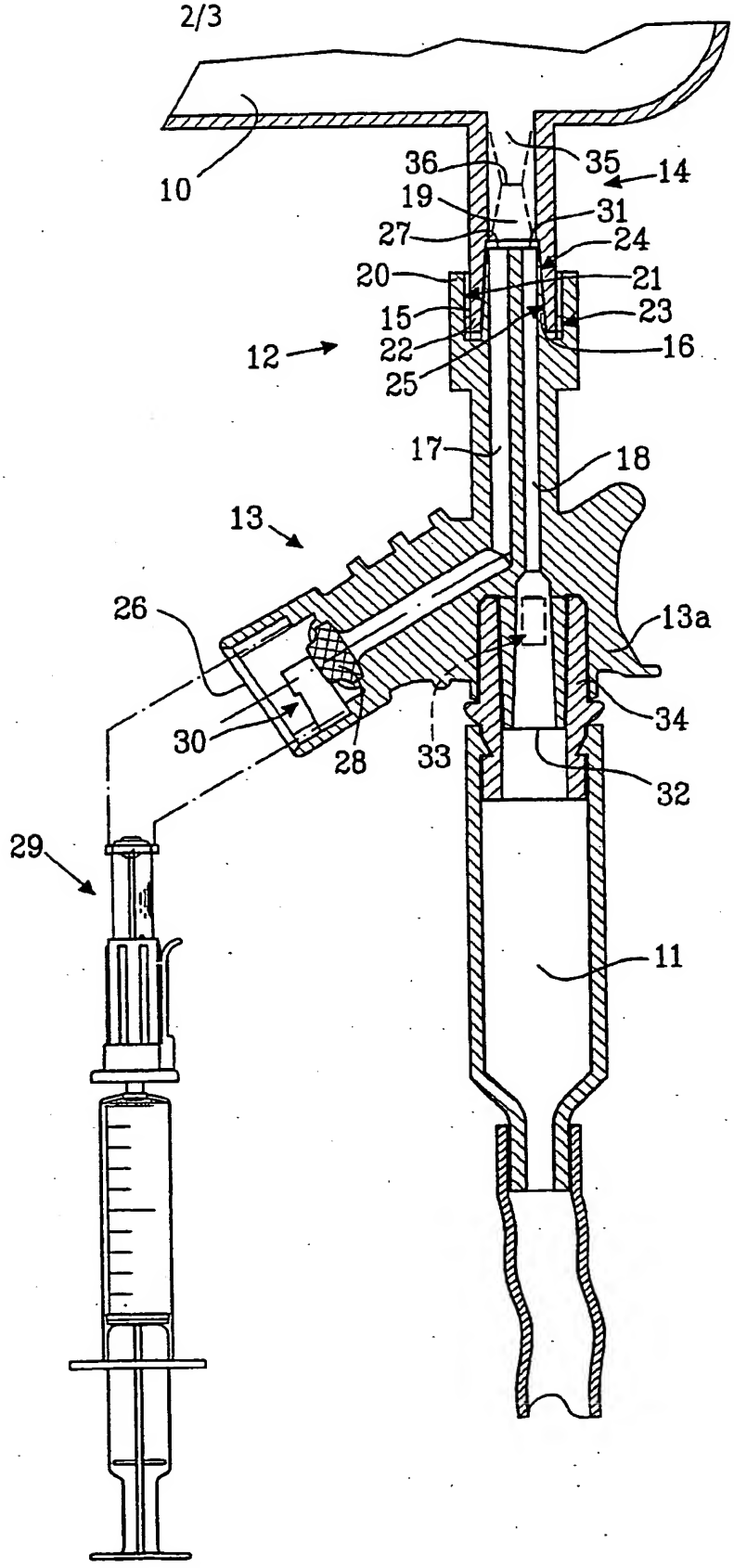
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FIG.2

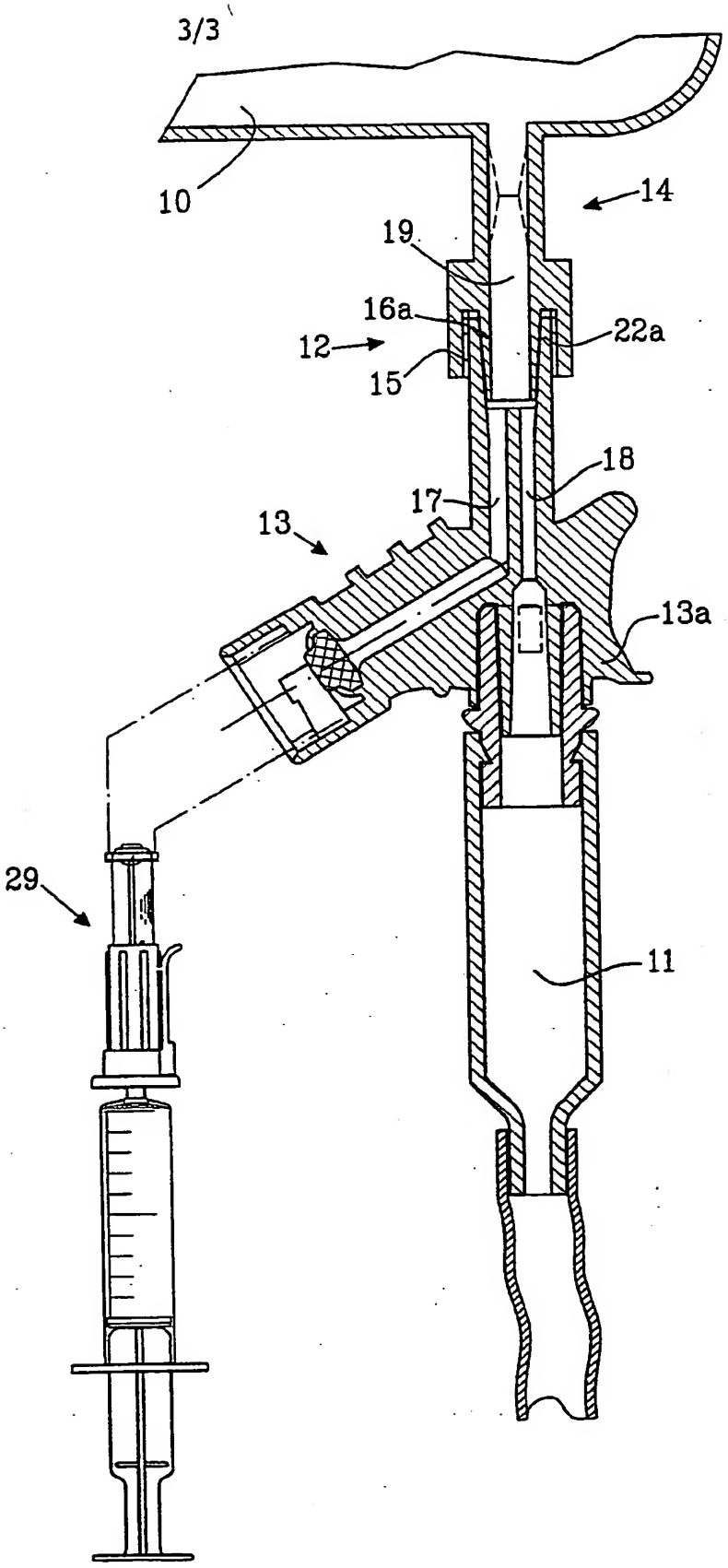

FIG.3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 03/01193

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61M 5/162, A61M 5/14, A61M 39/10, A61J 1/20
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61M, A61J

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-INTERNAL, WPI DATA, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 9819724 A1 (CARMEL PHARMA AB), 14 May 1998 (14.05.98), page 1, line 5 - line 14; page 1, line 23 - line 26; page 2, line 2 - line 5, figure 1, abstract	1-5,9-13,17, 18
A		6-8,14-16, 19-27
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Y	US 2002/0082586 A1 (MICHAEL J. FINLEY ET AL), 27 June 2002 (27.06.02), page 1, column 1, line 9 - line 12; page 1, column 1, line 56 - line 57; page 1, column 2, line 1 - line 5, figures 3,4, abstract	1-5,9-13,17, 18
A		6-8,14-16, 19-27
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[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
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Date of the actual completion of the international search	Date of mailing of the international search report
1 October 2003	07 -10- 2003
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Patrik Widerdal /OGU Telephone No. +46 8 782 25 00

Form PCT/ISA/210 (second sheet) (July 1998)

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PCT/SE 03/01193

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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